



Issues for the week ending August 1, 2025

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Legislative

# **Congressional Recess Underway**

The Senate has wrapped up its committee activity and adjourned for summer recess. The House adjourned last week and both chambers are scheduled to return to session after Labor Day on September 2.

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# Senate HELP Committee Holds Hearing on Affordability

On Thursday, the Senate Health, Education, Labor, and Pensions (HELP) Committee held a <u>hearing</u> on health care affordability. The panel examined strategies to reduce health care costs, including proposals to enhance competition, improve payment equity, increase transparency and protect consumer choice.

Chairman Bill Cassidy (R-LA) emphasized market-driven reforms and transparency to empower patients and lower costs. He highlighted the role employer sponsored insurance (ESI) in affordability and urged the Committee support for:

- S.1339, the PBM Reform Act (118th)
- Reform to the 340B program

On price transparency, he stated this is an important issue and noted the Trump Administration's actions to improve price transparency. He also criticized hospital facility fees, noting patients often pay 60-70% more at outpatient departments due to added charges, even when hospitals simply acquire clinics and rebrand them.

Ranking Member Bernie Sanders (I-VT) expressed deep concern about the provisions of the One Big Beautiful Bill Act (OBBBA), warning they could cause 15 million people to lose coverage, especially with the expiration of the enhanced premium tax credits. He also criticized health system consolidation, citing UnitedHealth's acquisition of 2,700 companies and stating it seems we are moving toward a private single-payer model run by the major insurer and reiterated his support for Medicare for All.

Despite partisan divides, there was broad agreement on the need to address opaque pricing, facility fees and PBM reform.

Senate Appropriations Committee Advances Health Funding Bill

On July 31, the Senate Appropriations Committee <u>marked up</u> its fiscal year (FY) 2026 Labor, Health and Human Services, Education, and Related Agencies (LHHS) funding bill by a 25-3 vote. The bill includes moderate increases in funding for rural health, mental health and substance use disorder, and maternal health research (bill text, report language).

While the House Appropriations Committee has advanced a majority of the 12 appropriations bills, it has not yet released the bill text for their FY26 LHHS bill. The Committee is expected to mark up its LHHS bill once Congress reconvenes.

**The Big Picture**: The House has only advanced two appropriations bills on the floor and the Senate has struggled to advance any. With the September 30 deadline quickly approaching it is likely there will need to be a deal on a continuing resolution to avert a government shutdown.

#### **Senators Pen Letter on No Surprises Act Implementation**

Senators Bill Cassidy (R-LA), Maggie Hassan (D-NH), and Roger Marshall (R-KS) sent a July 25 <u>letter</u> to HHS Secretary Kennedy, Department of Labor Secretary Lori Chavez-DeRemer, and Treasury Secretary Scott Bessent urging the Administration to finalize implementation of the No Surprises Act. The letter calls for rulemaking to implement good faith estimates and advanced explanations of benefits for patients.

#### Federal Issues

Regulatory

#### **CMS Releases Final IPPS, LTCH Payment Rules**

Last week, the Centers for Medicare & Medicaid Services (CMS) released its fiscal year (FY) 2026 payment rule for inpatient prospective payment system (IPPS) hospitals and long-term care hospitals (LTCH).

The rule includes a net increase of 2.6 percent over FY 2025 for IPPS hospitals, slightly higher than the 2.4 percent originally proposed. The net update includes a 3.3 percent market basket increase and 0.7 percent productivity cut. The rule also includes a \$2 billion increase for disproportionate share hospital (DSH) payments.

Absent congressional action, the Medicare-Dependent Hospitals and Low-Volume Hospital payments will expire on September 30, 2025. Should legislation be passed to extend these payments, CMS estimates these hospitals would receive about \$500 million in 2026.

In comments to CMS on the proposed IPPS rule, the hospital industry had warned that the previously proposed net increase of 2.4 percent was inadequate, especially given underwhelming increases over the previous four years and the unprecedented inflation and financial headwinds hospitals have experienced.

Under the final rule, LTCHs will see a net payment update of 3 percent compared to FY 2025. The final rule scales back from what had been proposed an increase in the threshold for high-cost outlier payments. Under the final rule, the outlier threshold will increase from \$77,048 to \$78,936, while outlier payments will increase by 0.3 percent.

Why this matters: In a <u>media statement</u> last week, the American Hospital Association expressed relief about the improvements to DSH payments and the lower-than-proposed increase in the outlier threshold for LTCHs but warned that the increases are not sufficient to address the significant challenges hospitals face.

The **final rule** is available online.

# **HRSA Announces 340B Rebate Pilot Program**

The Health Resources & Services Administration (HRSA) is inviting drug companies to apply for a voluntary, limited pilot program that will allow them to replace upfront 340B discounts with backend rebates on the 10 drugs that will be subject to Medicare Part D price caps starting in 2026. HRSA says it could choose to expand the list of drugs after next year following its evaluation of the effectiveness of the rebate model.

In a 340B program notice, HRSA said it intends to test the viability of a rebate model under which covered entities (CEs) would buy drugs at wholesale acquisition cost (WAC), submit rebate claims to drugmakers for drugs they dispense to eligible 340B patients, and receive rebates for the difference between WAC and the 340B price. The only drugs and drugmakers that would be eligible for the 2026 pilot program are:

- Januvia (Merck)
- Fiasp; Fiasp FlexTouch; Fiasp PenFill; NovoLog; NovoLog FlexPen; NovoLog PenFill (Novo Nordisk)
- Farxiga (AstraZeneca)
- Enbrel (Immunex)
- Jardiance (Boehringer Ingelheim)
- Stelara (Janssen)
- Xarelto (Janssen)
- Eliquis (Bristol Myers Squibb)
- Entresto (Novartis)
- *Imbruvica* (Pharmacyclics)

HRSA says participating drugmakers must allow CEs to submit rebate claims up to 45 calendar days from dispensing the drug to an eligible patient and must pay approved rebates within 10 calendar days of receiving the claims. The agency says drugmakers cannot deny a rebate claim based on their concerns about alleged diversion or Medicaid duplicate discounts, though they can do so for other reasons, such as if they already provided a 340B rebate to another CE on the same claim. HRSA says drug companies also can use the data it collects to "de-duplicate" 340B purchases and drug purchases that are subject to a Medicare maximum fair price (MFP) under the Inflation Reduction Act (IRA).

HRSA states that participating drugmakers may collect only limited data from CEs through the rebate claims process.

Eligible drugmakers that apply to participate in the limited rebate pilot program must submit plans to HRSA by Sept. 15 that specify how they will comply with the agency's requirements. The agency will announce whether it has approved those applications by Oct. 15, and the rebate plans it approves will take effect Jan. 1, 2026.

Although HRSA considers the notice announcing this limited rebate pilot program to be final, it will be collecting comments from stakeholders that are due Sept. 1.

Why this matters: Changes to the 340B payment model would reduce access to care and jeopardize hospitals' financial well-being if imposed, according to a new survey. 340B Health recently released the survey finding, which indicates that 340B hospitals would struggle to maintain current levels of uncompensated care if drugmakers' proposed rebate plan changes to the federal drug pricing program go into effect.

In 2024, five drug manufacturers—Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Novartis, and Sanofi—announced plans to replace upfront 340B discounts with rebates for some or all of their covered drugs. This means hospitals would be forced to purchase 340B drugs at wholesale rates, which are considerably higher than 340B discounted rates and then wait for manufacturers to approve and issue rebates.

With the rebate model, hospitals would be forced to "float" millions of dollars to pharmaceutical companies and many worry that the rebates won't be issued for the expected amount, or at all, impacting payroll and other expenses.

Here are some key takeaways from the survey:

- **Big money:** The average annual float per 340B hospital is estimated at \$72.2 million for Disproportionate Share Hospitals and \$1.7 million for Critical Access Hospitals.
- Jobs at risk: Rebate models threaten hospital payroll and financing abilities and could force layoffs even if hospitals receive every rebate they are owed. According to the survey, 27 percent of hospitals anticipate that waiting even one month for rebates could prevent them from making payroll and force layoffs.
- **Not hopeful:** Nearly all survey respondents expect Sanofi to deny at least some legitimate claims, with 87 percent expressing extreme concern.
- **Hurting, not helping:** Implementing the rebate model is expected to cost hospitals administrative expenditures on staffing, internal resource reallocation, and outsourcing to external vendors.
- Reduced access to care: The harm to patients would be even more severe if all manufacturers adopted rebate models. According to the study, 92 percent of hospitals would reduce the provision of discounted and/or free drugs at their pharmacy locations and 93 percent would face challenges maintaining current levels of uncompensated care.

On standby: As of July 2025, drugmakers have not yet implemented rebate models, as federal
courts continue to review the rebate issue in litigation filed by pharmaceutical companies against the
government.

Congress enacted the 340B Drug Pricing Program in 1992 to reduce the amount that eligible health care organizations have to pay for outpatient drugs prescribed to patients. In exchange for providing discounted drugs to 340B participants, pharmaceutical manufacturers may participate in the Medicare Part B and Medicaid programs. Covered organizations under 340B serve low-income, rural, and other vulnerable patient populations.

Read the **report** online.

# White House Directs Drug Manufacturers to Offer Most-Favored-Nation Pricing

The White House <u>called</u> on drug manufacturers to lower their U.S. prices for certain markets to align with Most-Favored-Nation (MFN) price targets, reflecting prices in European and other developed nations. In May, President Trump <u>instructed</u> manufacturers to offer MFN pricing under a direct-to-consumer (DTC) model promptly or face additional administrative action. The <u>letters</u> state manufacturers have not made sufficient progress and call for specific price reductions.

**Go Deeper:** President Trump's letters to 17 pharmaceutical manufacturers call on them to:

- Provide MFN pricing to every single Medicaid patient for their full portfolio of drugs.
- Guarantee U.S. purchasers will receive MFN pricing on all newly launched drugs.
- Negotiate harder with other developed nations for higher prices and, under an agreement with the federal government, repatriate all increased revenues to the US in the form of lower prices for patients and taxpayers.
- Establish DTC and Direct-to-Business (DTB) pharmaceutical sales in the U.S. at the MFN for high-volume, high-rebate drugs.

**What Happens Next:** The announcement and letters state the Administration is ready to work with manufacturers to achieve these results, including using trade policy to support higher prices abroad. If manufacturers "refuse to step up" and achieve these results, the Administration "will deploy every tool" in their arsenal to compel lower drug prices for Americans.

# Departments Release Surprise Billing TMA III FAQs

**What's new**: The Departments of Labor, Health and Human Services and the Treasury (Departments), released Frequently Asked Questions (FAQs) Part 71 which address implementation of the No Surprises Act (NSA) following the *Texas Medical Association v. HHS (TMA III)* court decision.

Why this matters: The Departments issued guidance for QPA calculation methodology while awaiting the results of the *TMA III* en banc rehearing. The Departments previously issued <u>guidance</u> that applied to qualifying payment amount (QPA) calculations for items and services furnished before Aug. 1, 2025, and parts of that guidance will now be extended or modified while the *TMA III* court case continues.

What they said: The FAQs include the following key elements:

- Qualifying Payment Amount (QPA) calculation methodology. Plans and issuers should calculate QPAs using a good faith, reasonable interpretation of the 2023 methodology until the Fifth Circuit Court issues its en banc decision. However, to reduce the burden of recalculating QPAs in accordance with the 2023 methodology, the Departments are extending the enforcement discretion for any plan or issuer that uses a QPA calculated in accordance with the 2021 methodology for items and services furnished before Feb.1, 2026. The Departments encourage States to adopt similar enforcement discretion. The Departments will reevaluate whether additional time for the enforcement relief is necessary after the TMA III en banc decision is released, and do not expect enforcement relief to be extended beyond Aug. 1, 2026.
- QPA Disclosures. Plans must continue to comply with disclosure requirements about the QPA. The
  Departments will exercise enforcement discretion for QPA disclosures, consistent with the updated
  guidance on QPA calculations, and encourage States to take similar action.

The FAQs also provide updated annual cost sharing limitations under the Affordable Care Act, including a new premium adjustment percentage and maximum out-of-pocket limit for the 2026 plan year.

CMS Publishes Early 2025 Snapshot and Full Year 2024 Effectuated Enrollment Report On July 24, 2025, CMS published information on average monthly effectuated enrollment and financial assistance for the Federally-facilitated Exchange (FFE) and State-based exchanges (SBEs) for February 2025 and the entire 2024 plan year. The Exchange data packages contain the following:

- Effectuated Enrollment: Early 2025 Snapshot and Full Year 2024 Average
- February Effectuated Enrollment Tables
- Full Year Effectuated Enrollment Tables

The release further includes 2024 issuer level enrollment data for the FFE.

Later, on July 30, 2025, CMS replaced a number of the files with updated files that contained minor technical corrections. The links above are the most up-to-date. CMS further released an additional file: First 5 Months 2025 Effectuated Enrollment Tables.

CMS Provides Update on Process for Cancelling Unauthorized Enrollments with Claims On July 28, 2025, in a presentation on CMS's Enrollment Issuer Policy call, CMS provided an update to the process for cancelling unauthorized enrollments (UEs) with claims. Under the new process, issuers will now be required to cancel policies with claims that meet the following criteria:

- 1. All other UE criteria are met (no premiums paid, no prior contact from enrollee).
- 2. The HICS narrative indicates, or the issuer otherwise knows, that the consumer is enrolled in another form of coverage (including employer-sponsored coverage).

Slides outlining this updated process can be found <u>here</u>. Those interested in reviewing the slides must have a REGTAP account to access them.

#### 2026 ACA Maximum Out-of-Pocket Limit

On July 30, 2025, the Departments of Labor, Health and Human Services, and Treasury released Frequently Asked Questions (FAQs) specifying the premium adjustment percentage and ACA maximum out-of-pocket limit for the 2026 plan year, which were finalized as part of the Marketplace Integrity and Affordability final rule. They are:

- Premium Adjustment Percentage: 1.6726771319; and
- <u>Maximum Out-of-Pocket Limit:</u> \$10,600 for self-only coverage, and \$21,200 for other than self-only coverage.

Please note that these values are only applicable for ACA plans. Separate guidance and values are released for high-deductible health plans.

# **Industry Trends**

Policy / Market Trends

# Coalition Outlines the Stakes if Congress Lets the Health Care Tax Credit Expire

The Keep Americans Covered (KAC) has <u>developed</u> a new educational resource for Congressional offices that offers a snapshot of the consequences ending the enhanced premium tax credits would have for their constituents.

**Additional Risks:** The resource also highlights how the promise of tax savings from the budget reconciliation bill is <u>at risk</u> if enhanced tax credits expire – as well as how voters overwhelmingly <u>support</u> the tax credits and will reward candidates who support their extension.

Read the KAC <u>letter</u> to bipartisan House and Senate leaders signed by over two dozen health care
organizations urging extension of the tax credits in the upcoming government funding bill.

# **Updates on Issuer Rate Filings, Impact of Expiration of Enhanced Premium Tax Credits**Average proposed rate increases by state for the individual market, with and without enhanced premium tax credits (eAPTCs), that have been made public since the last update are as follows:

Delaware: Average proposed rate increase of 35.6%; 28.2% if eAPTCs are extended

# White House Hosts "Make Health Tech Great Again" Event

The White House hosted a "Make Health Tech Great Again" Event with several technology companies in an effort to establish the infrastructure for a modernized digital health system focused on improving health outcomes and driving value-based care.

**The Focus:** A <u>press release</u> from CMS outlines the key areas the Administration is focused on, which include "promoting the CMS Interoperability Framework to easily and seamlessly share information between patients and providers, and increasing the availability of personalized tools so that patients have the information and resources they need to make better health decisions."

• An introductory video on CMS' Health Tech Ecosystem initiative can be viewed here.

**Pledge:** Several payers also signed a <u>pledge</u> "to participate in a CMS Aligned Network and work collaboratively to enable the CMS Interoperability Framework goals together."

#### **Additional Updates Include:**

- Revising CMS tools to enhance the beneficiary experience, such as the Plan Finder.
- Building a Fast Healthcare Interoperability Resources-based Application Programming Interface to enable apps to find **provider networks**.
- Adding modern digital identity to gov this year
- Developing infrastructure to reduce the time between when claims are received and when they become accessible through **Blue Button**.
- Integrating digital identity and National Provider Directory validation into data at the point of care.
- Establishing a new CMS-Aligned Networks concept based on the CMS Interoperability
   Framework.

**Go Deeper:** Read <u>additional information</u> on the new Living HHS Open Data Plan and refreshed HealthData.gov website.

#### AHIP Highlights the Value of HSAs to Nearly 39 Million Americans

AHIP released the results of a new nationwide survey that found a growing number of Americans are choosing to enroll in health savings account (HSA)-eligible health plans.

**The Bottom Line:** HSAs provide peace of mind to 38.8 million beneficiaries while allowing individuals and families flexibility and freedom to directly control their health care dollars.

#### **Key Findings:**

- **Continued robust growth** in the enrollment of people in HSA-eligible health plans. As of January 1, 2024, 38.8 million people were enrolled in HSA-eligible health plans, an increase from 32.1 million in 2019
- Large-group coverage, policies offered by employers with 50 or more employees, accounted for the majority of HSA-eligible health plan enrollment. As of January 1, 2024, 90% of HSA-eligible health plan enrollees were in the large group market.
- HSAs are a leading option for young working families to manage their health care expenses and provide peace of mind. 36% of HSA-eligible health plan enrollees were 25 to 44 years old, compared to 32% of all commercial enrollees Additionally, children 18 and younger accounted for 21% of the HSA-eligible health plan enrollment.

**Go Deeper:** Click here to view the full survey results.

# Trump Signs Executive Order Calling for Institutionalization of Homeless Individuals with SMI

President Trump signed an executive order titled "Ending Crime and Disorder on America's Streets." The order calls for policy changes to make it easier to remove homeless encampments, enforce encampment bans, and get homeless individuals into behavioral health treatment, including involuntary commitments of individuals that are deemed a risk to themselves or others to long-term institutional settings. It also aims to shift federal funding away from housing first policies to prioritize treatment in facilities that require sobriety and calls on the departments of Health and Human Services (HHS) and Housing and Urban Development to prioritize areas that are actively policing drug use and encampments to the fullest extent of the law when assessing federal grant programs. The Substance Abuse and Mental Health Services Administration (SAMHSA) would need to ensure that grants issued for harm reduction do not "facilitate illegal drug use." Read More

# Interested in reviewing a copy of a bill(s)? Access the following web sites:

Delaware State Legislation: http://legis.delaware.gov/.
New York Legislation: https://nyassembly.gov/leg/
Pennsylvania Legislation: www.legis.state.pa.us.
West Virginia Legislation: http://www.legis.state.wv.us/

For copies of congressional bills, access the Thomas website - http://thomas.loc.gov/.

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